

Kisunla® (donanemab-azbt)

Medicare Advantage

When requesting Kisunla® (donanemab-azbt), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Kisunla® is indicated for the treatment of Alzheimer's disease. Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials.

Coverage Guidelines

Alzheimer's disease

The individual must meet all of the following criteria for approval: [documentation required]

- Has a clinical diagnosis of mild cognitive impairment or mild dementia due to Alzheimer's disease;
- The presence of amyloid beta pathology consistent with Alzheimer's disease has been confirmed;
- Meets one of the following
 - The patient is receiving Kisunla as part of a CMS-approved prospective comparative study; OR
 - The patient is receiving Kisunla as part of a National Institutes of Health (NIH) supported clinical trial;

Approval duration: 12 months

Dosing Recommendations

Administer 700 mg as an intravenous infusion over approximately 30 minutes every four weeks for the first three doses, followed by 1400 mg every four weeks.

References

1. Kisunla™ (donanemab-azbt) [prescribing information]. Indianapolis, IN: Lilly; July 2024.
2. Alzheimer's Association. Alzheimer's disease facts and figures-2024. Available at: <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>. Accessed on July 9, 2024.
3. Sims JR, Zimmer JA, Evans CD, et al, for the TRAILBLAZER-ALZ 2 Investigators. Donanemab in early symptomatic Alzheimer disease: The TRAILBLAZER-ALZ 2 randomized clinical trial. *JAMA*. 2023;330(6):512-527.
4. Andrews JS, Desai U, Kirson NY, et al. Disease severity and minimal clinically important differences in clinical outcome assessments for Alzheimer's disease clinical trials. *Alzheimers Dement*. 2019;5:354-363.

5. Mintun MA, Lo AC, Duggan Evans C, et al. Donanemab in early Alzheimer's disease. *N Engl J Med*. 2021;384(18):1691-1704.
6. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) 200.3. [Version Number 1, Effective date: 04/07/2022. Revision date: 10/2024. Accessed March 11, 2025.
7. Centers for Medicare and Medicaid Services. Fact Sheet: CMS announces new details of plan to cover new Alzheimer's drugs. <https://www.cms.gov/newsroom/fact-sheets/cms-announces-new-details-plan-cover-new-alzheimers-drugs> - Issued 06/22/2023. Accessed February 22, 2024.